The House is adjourned till 12 o'clock.

The House then adjourned at two minutes past eleven of the clock.

The House re-assembled at twelve of the clock,

[MR. DEPUTY CHAIRMAN in the Chair]

WRITTEN ANSWERS TO STARRED QUESTIONS

Clinical trials without authorization

*341. SHRIMATI MOHSINA KIDWAI: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether Government are aware that clinical trials of drugs are being conducted by foreign multinationals on Indians without authorization from the patients and authorities;

(b) whether Government are also aware that these trials are being conducted without any clinical design;

(c) if so, whether Government have conducted any study to find out in the past three years how many new drugs or formulations have been tried on Indians by foreign drug companies and what has been its repercussions on the health of people; and

(d) if so, the details thereof and if not, the reasons therefor?

THE MINISTER OF HEALTH AND FAMILY WELFARE (DR. ANBUMANI RAMADOSS): (a) to (d) Government is not aware of any Global clinical trials being conducted by foreign multi-nationals on Indians without the permission of the Office of the Drugs Controller General of India {DCG(I)}. The permission to conduct any clinical trial with new drug in the country is a statutory requirement under Rule 122DA of Drugs and Cosmetics Rules, 1945.

Clinical Trials are an integral part of clinical and drug discovery research. The objective of clinical research and clinical trials in human beings is to establish safety and efficacy of molecules that promise therapeutic benefit for various diseases and disorders of human beings. The global regulatory agencies also insist for trials to be conducted for the new drugs on multi-ethnic population of the world to understand safety and efficacy issues due to ethnic variations.

Schedule-Y of D and C Act prescribes the requirements for conducting clinical trials in the country and data to be furnished for conducting clinical trials. Compliance to Good Clinical Practices is an important requirement of Schedule-Y.

Schedule-Y permits clinical trials for molecules discovered outside India and such clinical trials can be carried out by "multi-national pharmaceutical companies, local companies, global Clinical Research Organizations (CROs) and local CROs. For drugs discovered outside India, the concomitant clinical trails are permitted for Phase-II. Phase-III and Phase-IV and repeat Phase-I clinical trials are permitted to be conducted in India. The requirements specified under GCP and Schedule-Y have enough provisions to take care of ethical issues and safety of the subjects undergoing clinical trials.

The applicant for global clinical trials has to furnish detailed information with respect to objective of the study, participating countries, number of patients to be enrolled, approvals of institutional Review Board (Ethical Committee), details of serious adverse reactions reported, an affidavit indicating that the studies are not discontinued, safety data, animal pharmacology data, data of the previous Phases of clinical trials etc. for examination. After examination on the matter, an NOC is granted for conducting a trial with specific instructions about requirements of approval of ethical committee before starting of trial.

As per the requirements of Schedule-Y any unexpected serious adverse event (SAE) occurring during a clinical trial should be communicated by the investigator to the sponsor within 24 hours, by the investigator to the ethics committee within 7 working days, and by the Sponsor to the Licensing Authority and to the other Investigator(s) participating in the study within 14 calendar days.

During the past 3 years, 389 proposals for global Clinical trials were received. No serious adverse events have been reported so far.

Keeping in view the increase in the global and local clinical trials, the Government has made a provision in the Bill for amendment of the Drugs and Cosmetics Act, 1940, for creation of Central Drug Authority of India, recently introduced in the Rajya Sabha, by incorporating a clause for punishment for violation in conducting of clinical trials which provides for an imprisonment of 5 years and a fine up to Rs. 10 lakhs for first offence and for subsequent offences imprisonment of 10 years and a fine of Rs. 20 lakhs. The Bill has now been referred to the Parliamentary Standing Committee.

New pharma policy

*342. SHRI RAVI SHANKAR PRASAD:
DR. M.A.M. RAMASWAMY:

Will the Minister of CHEMICALS AND FERTILIZERS be pleased to state:

(a) whether Government are aware of the fact that large scale pharma companies are behind delay in announcing the New Pharma Policy by the Government; and